

REMARKS

The non-final Office Action mailed May 12, 2005 has been received and carefully reviewed. Original claims 1-66 are pending. None of the claims have been amended. Reconsideration of the application and withdrawal of the present rejections are respectfully requested in view of the following remarks.

The statutory rejections were listed as follows:

Claims 1-2, 4-42, 44-55 and 63-66 stand rejected under 35 U.S.C. § 102(b) as being anticipated by *Altman et al.* (U.S. Patent No. 6,416,510).

Claim 3 stands rejected under 35 U.S.C. § 103(a) over *Gray* (U.S. Patent No. 6,144,879); claim 43 stands rejected under § 103(a) over *Altman* in view of *Stokes* (U.S. Patent No. 4,506,680); and claims 59-62 stand rejected under § 103(a) over *Altman* in view of *Schroepel et al.* (U.S. Patent No. 5,749,909).

Concerning the anticipation rejection of claims 1-2, 4-42, 44-55 and 63-66 in view of *Altman*, Applicant respectfully disagrees with the Examiner's characterization of *Altman*, and the contention that *Altman* anticipates these claims. Applicant respectfully asserts that several features recited in independent claims 1, 18, 33, 48, and 55 are not disclosed, expressly or inherently, in *Altman* or in any other art of record.

To anticipate a claim, the asserted reference must clearly and unequivocally disclose every element and recitation of the claimed invention. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the claim. All claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102.

Respectfully, Applicant disagrees with the characterization of the *Altman* teachings and of Applicant's claimed invention presented in the Office Action. In the Office Action, the Examiner states that the catheter disclosed in *Altman* is considered to

anticipate Applicant's claimed lead because both devices extend into the patient's heart and connect with electrodes that contact the myocardium for sensing the heart's electrical signals. The Examiner further states that the electrode disclosed in *Altman* is considered to anticipate Applicant's claimed electrode because both are positionally stabilized within subcutaneous tissue surrounding the catheter or lead.

Many of Applicant's claims recite an electrode configured for subcutaneous non-intrathoracic placement. Respectfully, the Examiner appears not to give sufficient patentable weight to Applicant's claim language directed to such an electrode that is configured for placement in subcutaneous non-intrathoracic tissue. Those skilled in the art clearly understand the term "intrathoracic" to mean *within the cavity of the chest*. See, e.g., *Stedman's Medical Dictionary*, 25th ed. 1989, page 796. Those skilled in the art also clearly understand the term "non-intrathoracic" to mean NOT within the cavity of the chest.

Altman teaches an electrode having a helical coil or other fixation and penetrating element that engages and penetrates the myocardium. The myocardium is cardiac tissue residing within the heart. The *Altman* electrode is configured specifically for placement within the thoracic cavity. Hence, *Altman* clearly fails to teach an electrode configured for placement in subcutaneous non-intrathoracic tissue. Respectfully, the Examiner's characterization of Applicant's claimed structure and the teachings of *Altman* are in error.

Moreover, each of the rejected independent claims 1, 18, 33, 48, and 55 recites, in various forms, an arrangement or method that provides for phoresis delivery of a pharmacological agent from an implantable lead or can to subcutaneous tissue. As Applicant's specification teaches at page 12, lines 1-11, phoresis delivery of a pharmacological agent can be implemented in a variety of ways, two non-limiting examples of which are electrophoresis and sonophoresis:

Electrophoresis is generally understood as an electrochemical process in which colloidal particles and/or macromolecules with a net electric charge migrate under the influence of an electric potential. For purposes herein, electrophoresis is synonymous with ionophoresis, iontophoresis, and dielectrolysis.

Sonophoresis is generally understood as a sonochemical process in which colloidal particles and/or macromolecules migrate under the influence of pressure waves, such as continuous wave or burst-mode ultrasound. For purposes herein, sonophoresis is synonymous with sonophoresis. Phoresis based technologies such as, for example, electrophoresis and sonophoresis, may be used in accordance with the present invention to impel pharmacological agents into tissue.

Altman discloses a drug delivery system that includes a drug pump, a reservoir, and a drug delivery catheter. *Altman* wholly fails to teach, expressly or inherently, an arrangement or method that provides for phoresis delivery of a pharmacological agent from an implantable lead or can to subcutaneous tissue.

The disclosure in an anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. Mayo Foundation for Medical and Education Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003). See, also, MPEP § 2121.01. Applicant respectfully asserts that *Altman*'s description of an endocardial helical electrode and conventional drug pump delivery system is insufficient to support the Examiner's anticipation rejection of Applicant's claims. It is unclear how one skilled in the art could arrive at Applicant's claimed structure using *Altman*'s myocardial electrode fixation and drug pump delivery system teachings without undue experimentation.

Clearly, *Altman* does not teach each and every element as set forth in independent claims 1, 18, 33, 48, and 55, either expressly or inherently. Applicant's identical invention articulated in claims 1, 18, 33, 48, and 55 is clearly not shown in as complete detail in *Altman* as is contained in these claims. Because all claim elements, and their limitations, are not found in *Altman*, a rejection of claims 1, 18, 33, 48, and 55 based on 35 U.S.C. §102 can not be maintained.

While Applicant does not acquiesce with the particular anticipation rejections of the dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claim 1, 18, 33, 48, and 55. The claims

that depend from 1, 18, 33, 48, and 55 include all of the limitations of their respective base claims and any intervening claims, and recite additional features which further distinguish these claims from *Altman* and the other art of record. Accordingly, all dependent claims subject to an anticipation rejection are patentable over *Altman*.

Concerning the several obviousness rejections listed above, Applicant respectfully asserts that the several elements and limitations missing in the *Altman* teachings are not supplied by *Gray*, *Stokes*, or *Schroepfel*. None of these references, alone or in combination, teaches or suggests a cardiac electrode configured for subcutaneous non-intrathoracic placement within a patient or an arrangement or method that provides for phoresis delivery of a pharmacological agent from an implantable lead or can to subcutaneous tissue. For at least these reasons, claims 3, 43, and 59-62 are not rendered obvious over any combination of *Altman*, *Gray*, *Stokes*, and *Schroepfel*.

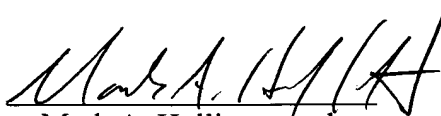
It is believed that the claims 1-66 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if there are any questions regarding the above new claims or if prosecution of this application may be assisted thereby.

Respectfully submitted,

Hollingsworth & Funk, LLC
8009 34th Avenue South, Suite 125
Minneapolis, MN 55425
(952) 854-2700

Date: July 29, 2005

By:



Mark A. Hollingsworth
Reg. No. 38,491